§ 486.108

§ 486.108 Condition for coverage: Safety standards.

X-ray examinations are conducted through the use of equipment which is free of unnecessary hazards for patients, personnel, and other persons in the immediate environment, and through operating procedures which provide minimum radiation exposure to patients, personnel, and other persons in the immediate environment.

(a) Standard—tube housing and devices to restrict the useful beam. The tube housing is of diagnostic type. Diaphragms, cones, or adjustable collimators capable of restricting the useful beam to the area of clinical interest are used and provide the same degree of protection as is required of the housing.

(b) Standard—total filtration. (1) The aluminum equivalent of the total filtration in the primary beam is not less than that shown in the following table except when contraindicated for a particular diagnostic procedure.

Operating kVp	Total filtration (inherent plus added)
Below 50 kVp 50–70 kVp Above 70 kVp	0.5 millimeters aluminum. 1.5 millimeters aluminum. 2.5 millimeters aluminum.

(2) If the filter in the machine is not accessible for examination or the total filtration is unknown, it can be assumed that the requirements are met if the half-value layer is not less than that shown in the following table:

Operating kVp	Half-value layer
50 kVp	2.6 millimeters aluminum. 2.8 millimeters aluminum. 3.0 millimeters aluminum.

- (c) Standard—termination of exposure. A device is provided to terminate the exposure after a preset time or exposure.
- (d) Standard—control panel. The control panel provides a device (usually a milliammeter or a means for an audible signal to give positive indication of the production of X-rays whenever the X-ray tube is energized. The control panel includes appropriate indicators (labelled control settings and/or meters) which show the physical factors

(such as kVp, mA, exposure time or whether timing is automatic) used for the exposure.

- (e) Standard—exposure control switch. The exposure control switch is of the dead-man type and is so arranged that the operator can stand at least 6 feet from the patient and well away from the useful beam.
- (f) Standard—protection against electrical hazards. Only shockproof equipment is used. All electrical equipment is grounded.
- (g) Standard—mechanical supporting or restraining devices. Mechanical supporting or restraining devices are provided so that such devices can be used when a patient must be held in position for radiography.
- (h) Standard—protective gloves and aprons. Protective gloves and aprons are provided so that when the patient must be held by an individual, that individual is protected with these shielding devices.
- (i) Standard—restriction of the useful beam. Diaphragms, cones, or adjustable collimators are used to restrict the useful beam to the area of clinical interest.
- (j) Standard—personnel monitoring. A device which can be worn to monitor radiation exposure (e.g., a film badge) is provided to each individual who operates portable X-ray equipment. The device is evaluated for radiation exposure to the operator at least monthly and appropriate records are maintained by the supplier of portable X-ray services of radiation exposure measured by such a device for each individual.
- (k) Standard—personnel and public protection. No individual occupationally exposed to radiation is permitted to hold patients during exposures except during emergencies, nor is any other individual regularly used for this service. Care is taken to assure that pregnant women do not assist in portable X-ray examinations.

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